DEC 1 5 2003

CIBA Vision. A Novartis Company	CIBA Vision® Corporation 11460 Johns Creek Parkway Duluth, GA USA 30097	Page 1 of 4

Focus® DAILIES®, Focus® DAILIES® Toric and Focus® DAILIES® Progressives
(nelfilcon A) ONE-DAY Soft Contact Lenses

510(k) Summary of Safety and Effectiveness

510(k) Summary

K033701

1. Submitter Information:

Company: CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia USA 30097

Contact Person: Alicia M. Plesnarski, RAC
Director, Global Regulatory Affairs
Telephone: 678-415-3924
FAX: 678-415-3454

Date Prepared: 24 November 2003

2. Device Name:

- Common Name: Soft Contact Lens
- Trade/Proprietary Name: Focus® DAILIES®, Focus® DAILIES® Toric and Focus® DAILIES® Progressives (nelfilcon A) ONE-DAY CONTACT LENS
- Classification Name: Daily Wear Soft (hydrophilic) Contact Lens
- Device Classification: Class II [21 CFR 886.5925 (b) (1)]

3. Predicate Device(s):

Lens Material: CIBA Vision's Focus® DAILIES® (nelfilcon A) One-Day Contact Lens

Clear lenses (spherical & toric):	K943487
VISITINT® lenses:	K984273
Manufacturing Change-Surfactant Additive:	K010636

Multifocal Design: CIBA Vision's Focus® DAILIES® Progressives (nelfilcon A) One-Day
Visitint lenses: K003826

4. Description of Device:

The Focus® DAILIES®, Focus® DAILIES® Toric and Focus® DAILIES® Progressives (nelfilcon A) ONE-DAY CONTACT LENS are daily wear soft contact lenses intended for single use daily disposable wear. The Dailies lens is a spherical soft contact, Dailies toric lenses have a double thin zone design, and the Dailies Progressives lens is a progressive aspheric simultaneous vision soft contact lens. A constant near power profile is incorporated into each Progressive lens across the full range of distance powers. The near and intermediate powers are concentrated primarily in the central portion of the optical zone while the surrounding portion is weighted toward distance. The continuous changes in power across the surface of the lens allow patients

requiring a reading addition of up to +3.00 diopters to see clearly at far, intermediate and near distances.

The lens material is 69% water and 31% nelfilcon A polymer (polyvinyl alcohol partially acetalized with N-formylmethyl acrylamide). The lenses are clear or tinted from edge to edge for visibility purposes with the color additive copper phthalocyanine (CuP).

Lenses are supplied sterile in foil sealed blister packs containing isotonic phosphate-acetate buffered saline solution. The package storage saline may contain up to 0.02% Poloxamer 108.

The physical properties of the lens are:

- Refractive Index: 1.38 (hydrated)
- Center Thickness: 0.09 to0.17 mm (0.10 at -3.00D; 0.15 at +3.00D)
- Light Transmittance: 96% (approx)
- Oxygen Permeability (Dk): 26×10^{-11} (cm^2/sec) (ml O_2/ml x mm Hg) [35° C, Fatt corrected]
- Water Content: 69% by weight in normal saline

5. Indications for Use:

Focus® DAILIES® and Focus® DAILIES® Toric (nelfilcon A) One-Day soft contact lenses are indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia and astigmatism) in not aphakic persons with non-diseased eyes.

Focus® DAILIES® Progressives (nelfilcon A) One-Day soft contact lenses are indicated for daily wear for the optical correction of presbyopia in not aphakic persons with non-diseased eyes who require a reading addition of +3.00 diopters (D) or less and who may have 2.00 diopters (D) or less of astigmatism that does not interfere with visual acuity.

The lenses are to be prescribed for single use daily disposable wear. DAILIES® lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

6. Description of Safety and Substantial Equivalence

6.1 Comparison to Predicate Device (s):

- Lens Material [Predicate Lens current Focus DAILIES (nelfilcon A)]:
  Lens material, chemical composition, formulation (except for addition of the manufacturing additive), manufacturing process, packaging and the sterilization method and cycle remain unchanged from the descriptions previously provided in cleared Premarket Notifications 510(k) K963487, K984273, K992446, K003826, K010636.

- Lens Design:
  No change to established spherical, toric or multi-focal lens designs.

Table 1: Comparison to CIBA Vision's Predicate Device

	Predicate Device	
	Focus DAILIES (nelfilcon A) made without additive	Focus DAILIES (nelfilcon A) made with additive
Lens Material:	nelfilcon A	nelfilcon A
Material Classification:	FDA Group 2 (> 50% H_2O, nonionic polymer)	FDA Group 2 (> 50% H_2O, nonionic polymer)
Water Content:	69.4%	68.4%
Light Transmittance (clear lenses):	100%	100%
Oxygen Permeability (Dk, Coulometric):	~ 25 barrer	25.86 barrer
Power Range:	+20.00 to -20.00D	+20.00 to -20.00D
Visibility Tint:	With or without Copper Phthalocyanine	With or without Copper Phthalocyanine
Manufacturing Method:	Full Mold Cast Lightstream Technology	Full Mold Cast Lightstream Technology
Lens Design:	Spherical and/or Multi-focal	Spherical and/or Multi-focal
Sterilization:	Steam sterilization, Validated autoclave	Steam sterilization, Validated autoclave
Packaging:	Blister Pack	Blister Pack
Package Storage saline solution	Phosphate-acetate buffered saline with up to 0.02% Poloxamer 108	Phosphate-acetate buffered saline with up to 0.02% Poloxamer 108

6.2 Non-clinical Testing:

Results from a series of physical/chemical tests confirm that DAILIES lenses made with or without the manufacturing additive were equivalent and within established specifications for the lenses. Successful results from in-vivo and in-vitro toxicology tests confirm the lenses remain non-toxic and biocompatible with the ocular environment.

6.3 Clinical Testing:

A one-month clinical study demonstrated similar overall performance to the concurrent predicate control in the clinically relevant areas of vision, health, and comfort and fit when worn for daily wear.

7. Substantial Equivalence

DAILIES lenses made with or without the manufacturing additive are equivalent and within established specifications for the lens. The lenses maintain clinical performance expectations, established physical/chemical characteristics, and are stable and biocompatible with the ocular environment.

Any differences which may exist between lenses made with or without the additive do not adversely affect the established performance characteristics and safety and effectiveness profile of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 15 2003

Alicia M. Plesnarski
Director, Global Regulatory Affairs
CIBA Vision Corporation
11460 Johns Creek Parkway
Duluth, Georgia 30097-1556

Re: K033701
Trade Name: Focus® DAILIES®, Focus® DAILIES® Toric and Focus® DAILIES® Progressives (nelfilcon A) One-Day Contact Lenses for Daily Wear
Regulation Number: 21 CFR 886.5925
Regulation Name: Soft (hydrophilic) Contact Lens
Regulatory Class: Class II
Product Code: LPL; MVN
Dated: November 24, 2003
Received: November 28, 2003

Dear Ms. Plesnarski:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 594-4613. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

A. Ralph Rosenthal, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

PART III. INDICATIONS FOR USE STATEMENT

510(k) Number:

Device Name(s): **Focus® DAILIES®, Focus® Toric, Focus® DAILIES® Progressives (nelfilcon A) One-Day Contact Lens**

Indications For Use:

Focus® DAILIES® and Focus® DAILIES® Toric (nelfilcon A) ONE-DAY CONTACT LENSES are indicated for daily wear for the optical correction of refractive ametropia (myopia, hyperopia and astigmatism) in not-aphakic persons with non-diseased eyes.

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The lenses are to be prescribed for single-use daily disposable wear. DAILIES lenses are not intended to be cleaned or disinfected and should be discarded after a single use.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic Ear, Nose and Throat Devises

510(k) Number K032701